

In th Claims:

Please cancel claims 7 to 31 without prejudice and add new claims 32 to 53:

Claims 1 to 6 (previously canceled).

Claims 7 to 31 (canceled).

32(new). A method of manufacturing a bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said method comprising embedding testosterone and/or one or more testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary agent, by a spray-drying process, so as to form an amorphous active ingredient premix;

wherein said one or more testosterone ester comprises a respective carboxylic acid radical with from 1 to 20 carbon atoms.

33(new). The method as defined in claim 32, wherein said respective carboxylic acid radical is linear, branched, alicyclic, saturated and/or unsaturated and said respective carboxylic acid radical has up to five double and/or triple bonds.

34(new). The method as defined in claim 32, wherein said amorphous active ingredient premix comprises said testosterone and said one or more testosterone ester in a ratio of said testosterone to said one or more testosterone ester of from

1 : 100 to 1 : 1.

35(new). The method as defined in claim 34, wherein said ratio is from 1 : 10 to 1 : 5.

36(new). The method as defined in claim 35, wherein said spray-drying process comprises spray-drying a solution of said organic polymer, said testosterone and/or said one or more testosterone ester and said at least one auxiliary ingredient in a solvent.

37(new). The method as defined in claim 36, wherein said solvent is ethanol and said organic polymer is polyvinyl pyrrolidone or hydroxypropyl-methylcellulose.

38(new). The method as defined in claim 32, further comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form a mixture and compressing said mixture to form said bioadhesive tablet.

39(new). The method as defined in claim 32, further comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing an adhesive layer mixture and compressing the active ingredient layer mixture together with the adhesive layer mixture to form said bioadhesive tablet with a bi-layer structure.

40(new). The method as defined in claim 39, wherein said at least one auxiliary ingredient is selected from the group consisting of binders, fillers, lubricants, surfactants and a disintegration accelerator and said adhesive layer mixture comprises a bioadhesive polymer.

41(new). The method as defined in claim 32, further comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing at least one other layer mixture including an adhesive layer mixture and compressing the active ingredient layer mixture together with the at least one other layer mixture to form said bioadhesive tablet with a multi-layer structure.

42(new). The method as defined in claim 32, wherein said one or more testosterone ester has an ester group, said one or more testosterone ester is selected according to chain length and steric structure of said ester group, and wherein respective dosages of said testosterone and said one or more testosterone ester in said bioadhesive tablet are selected, so that a predetermined testosterone blood level in said person is provided when said bioadhesive tablet is administered to said person.

43(new). The method as defined in claim 32, wherein said one or more testosterone ester is selected from the group consisting of testosterone acetate, testosterone propionate, testosterone enantate, testosterone cipionate,

testosterone cyclohexanecarboxylate, testosterone undecanoate and testosterone bucylate, so that said testosterone blood level in said person varies according to an endogenous circadian body rhythm when said bioadhesive tablet is administered to said person.

44(new). The method as defined in claim 32, wherein said one or more testosterone ester includes testosterone undecanoate and wherein said testosterone and said testosterone are embedded together in said organic polymer, in order to provide an extended time-release half-life.

45 (new). A bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said bioadhesive tablet being made by a method comprising embedding testosterone and/or one or more testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary agent, by a spray-drying process, so as to form an amorphous active ingredient premix;

wherein said one or more testosterone ester comprises a respective carboxylic acid radical with from 1 to 20 carbon atoms.

46(new). The tablet as defined in claim 45, wherein said respective carboxylic acid radical is linear, branched, alicyclic, saturated and/or unsaturated and said respective carboxylic acid radical has up to five double and/or triple bonds.

47(new). The tablet as defined in claim 45, wherein said amorphous active ingredient premix comprises said testosterone and said one or more testosterone ester in a ratio of said testosterone to said one or more testosterone ester of from 1 : 100 to 1 : 1.

48(new). The tablet as defined in claim 47, wherein said ratio is from 1 : 10 to 1 : 5.

49(new). The tablet as defined in claim 47, wherein said spray-drying process comprises spray-drying a solution of said organic polymer, said testosterone and/or said one or more testosterone ester and said at least one auxiliary ingredient in a solvent.

50(new). The tablet as defined in claim 49, wherein said solvent is ethanol and said organic polymer is polyvinyl pyrrolidone or hydroxypropyl-methylcellulose.

51(new). The tablet as defined in claim 45, wherein said method comprises mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form a mixture and compressing said mixture to form said bioadhesive tablet.

52(new). The tablet as defined in claim 45, wherein said method comprises mixing said amorphous active ingredient premix with at least one auxiliary

ingredient to form an active ingredient layer mixture, preparing an adhesive layer mixture and compressing the active ingredient layer mixture together with the adhesive layer mixture to form said bioadhesive tablet with a bi-layer structure.

53(new). The tablet as defined in claim 45, wherein said method comprises mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing at least one other layer mixture including an adhesive layer mixture and compressing the active ingredient layer mixture together with the at least one other layer mixture to form said bioadhesive tablet with a multi-layer structure.

REMARKS

I. Claim Changes

In response to the rejections under 35 U.S.C. 103 (a) based on Voorspoels, et al, and Timpe (in the case of claims 13 to 31), claims 7 to 15 for a method of controlling testosterone blood level by administration of an effective amount of a mixture of testosterone and at least one testosterone ester have been canceled without replacement.

New claims 32 to 53 have been filed. These new claims include new claims 32 to 44 for a method of manufacturing bioadhesive tablets for controlling testosterone blood level in a person. The key step that distinguishes from the